

U.S. App. No.: 09/978,261  
Filed: October 15, 2001

### **REMARKS**

Applicants and Applicants' representatives wish to thank Primary Examiner Frank Lu and his Supervisor for the courtesy extended during the April 5, 2006 Interview. At the interview Applicants' representatives discussed the Wang reference and the arguments for distinguishing the Wang reference set out below.

Claims 40 - 52 are currently pending and under examination. Claims 40 - 52 stand rejected. Upon entry of this Amendment, claims 40 - 52 will be pending and under examination. Claims 40 and 47 are independent. Applicants respectfully request consideration of claims 40 - 52 in light of the remarks that follow.

#### **Claims 40 – 52 are in Condition for Allowance**

As discussed in the April 5, 2006 interview, Applicants respectfully submit that the previously cited Wang reference (U.S. Patent No. 5,567,583), alone or in combination, fail to teach or suggest the limitations set forth in claims 40 - 52. Specifically, Wang does not teach limitation “a moiety capable of quenching, masking or inhibiting the activity of the signal generating moiety when located adjacent to, or in close proximity to the signal generating moiety” (claim 40(b)(ii)(B) and claim 47(a)(ii)(B)) or limitation “when the first primer and the second primer are bound to one another, the signal is inhibited” (claim 40(b)(iii) and claim 47(a)(iii)). Wang does not teach that the acceptor fluorophore actually quenches that signal of the donor fluorophore. Indeed, all of the examples in Wang disclose a donor:acceptor pair that displays a signal when in close proximity to each other and that the signal decreases upon amplification of the target nucleic acid (Example IV, column 12, lines 59 – 63; Figure 5). This is in direct contrast to the primer pair of the claimed invention. The limitation of claims 40 and 47

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specifically states that “when the first primer and the second primer are bound to one another, the signal is inhibited.” Furthermore, a word search of the Wang reference failed to locate the terms: quenching, inhibiting or masking.

Applicants also respectfully maintain that Wang does not teach limitation “amplifying the target nucleic acid and separating the signal generating moiety and the quenching, masking or inhibitory moiety, thereby generating a signal, wherein detection of an increase in the signal indicates the presence of the target nucleic acid in the sample” (claim 40(d) and claim 47(d)) Wang describes a donor:acceptor pair that displays a signal when in close proximity to each other and whose signal decreases upon amplification of the target nucleic acid. Therefore, the end point measurement at the conclusion of the amplification process disclosed in Wang is exactly opposite what would be measured at the conclusion of the amplification process recited in claim 47. Further, while performing the Wang method, one would have to measure a decrease in signal, which is inherently ambiguous and not as advantageous as measuring an increase in signal. The decrease in signal could mean that one has a positive result or it could indicate that the assay did not adequately perform.

Applicants maintain that Wang does not teach each and every element of claims 40 and 47 and therefore cannot anticipate the claims. Furthermore, Applicants maintain that it would not be obvious to one having ordinary skill in the art at the time the invention was made to perform the method recited in claims 40 and 47, in view of Wang.

For the reasons stated above, Applicants maintain that a the statutory requirements of a U.S.C. §102(b) or U.S.C. § 103(a) rejection have not been met. Therefore, the rejections of

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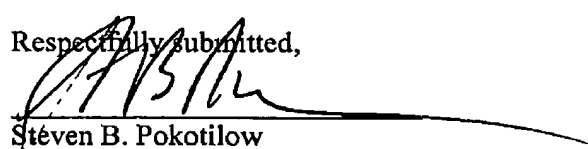
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claims 40 - 52 should be withdrawn and, accordingly, notice that claims 40 - 52 are in condition for allowance is requested.

### CONCLUSION

Applicants respectfully submit that this application is in condition for allowance. Early and favorable action is earnestly solicited. No fee, except for the fee in connection with the two month extension fee, is believed due in connection with the filing of this Response. However, if any additional fees are due the amount of such fee may be charged to Deposit Account No. 19-4709.

Respectfully submitted,



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